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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/084,471	05/22/98	MURPHY	P 5871.01.US02

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HOWREY SIMON ARNOLD & WHITE LLP  
BOX 34  
1299 PENNSYLVANIA AVENUE NW  
WASHINGTON DC 20004

EXAMINER

ZITOMER, S

ART UNIT	PAPER NUMBER
1655	12

DATE MAILED: 12/01/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Office Action Summary</b>	Application No. <b>09/084,471</b>	Applicant(s) <b>MURPHY et al.</b>
	Examiner <b>Stephanie Zitomer</b>	Group Art Unit <b>1655</b>

Responsive to communication(s) filed on Sep 18, 2000.

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

Claim(s) 61-86 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 61-86 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

## DETAILED ACTION

### Application status

1. Receipt of the amendment filed September 18, 2000 is acknowledged.
2. All of the objections and rejections set forth in the previous Office action, paper no. 9, mailed March 16, 2000 are withdrawn as moot in view of cancellation of claims 1-60 and amendments to the specification.

### Objection to the specification: Lack of proper antecedent basis

3. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP. § 608.01(o). Correction of the following is required: In the amendment filed September 18, 2000 (page 8) support for the nucleotide changes in new claims 61-86 is pointed out in Figures 1-3 and SEQ ID NOS:2-13. However, such support is not found because the exon sequences in the figures have no nucleotide numbers and in the Sequence Listing each exon is a separate sequence with its own nucleotide numbering independent of the BRCA2 gene sequence nucleotide numbering, which BRCA2 gene sequence is not identified in the claims or in the specification in any case.

*The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.*

### Rejection under 35 U.S.C. 112, first paragraph: New matter

4. Claims 84-86 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims contain new subject matter for which descriptive support is not found in the specification. The new subject matter is the negative limitation, "not an adenine" *et al.* Applicant is reminded that a negative limitation in a claim must have basis in the original disclosure. The mere absence of a positive recitation is not a basis for an exclusionary limitation. *Ex parte Grasselli*, 231 USPQ 393 (Bd. App. 1983), *aff'd mem.*, 738 F.2d 453 (Fed. Cir. 1984).

### Rejection under 35 U.S.C. 112, first paragraph: Lack of proper written description

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Claims 61-86 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are interpreted as broadly drawn to any BRCA2 coding sequence comprising the recited nucleotide sequence comprising any exon 15 (16) sequence that contains a designated nucleotide at a position "corresponding to" the recited positions in SEQ ID NO:2-4 or 6, a nucleotide sequence comprising SEQ ID NO:2 or SEQ ID NO:3 or a nucleotide sequence comprising a sequence that encodes a given amino acid at a position "corresponding to" a given position in a given amino acid sequence. Thus, the claims are drawn to a large genus of BRCA2 sequences for which the application discloses only five species (SEQ ID NOS:4, 6, 8, 10, 12). A Genbank sequence is also referenced at page 6. According to the specification at page 2, many BRCA2 genes are known in the art inclusive of the many mutations and normal polymorphisms already reported. However, neither the claims nor the specification identify the nucleotide positions in the claimed BRCA2 gene or any BRCA2 gene that "correspond to" the nucleotide positions set forth in the claims in SEQ ID NOS:2-4, 6, 8, 10 and 12. Disclosure of the partial structure, i.e., the 71 defined nucleotides, does not provide a basis for predicting the nucleotides at the other 10411 positions in the coding sequence absent description in the specification of a nexus between the defined and undefined individual nucleotides in the claimed sequences. The problem is the same with claims 72-82 because the recitation "an amino acid position corresponding to" encompasses a large genus of unknown amino acid sequences containing a position "corresponding to" the given position. In addition to enablement the first paragraph of 112 requires a "written description". As set forth by the Court in *Vas-Cath Inc. v. Mahurkar*, 19 USPQ2d 1111, the written description must convey to one of skill in the art "with reasonable clarity" that as of the filing date applicant was in possession of the claimed invention.

**Rejections under 35 U.S.C. 112, second paragraph: Indefinite claims**

5. Claims 61-86 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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(a) The claims are indefinite and have not been examined with respect to the prior art because the exon positions and "coding sequence" positions are not identified in the claims or elsewhere in the disclosure. It is not possible to search a "nucleic acid molecule comprising a BRCA2 gene" having the limitations recited in the claims without knowing the nucleotide sequence of the BRCA2 gene, the nucleotide positions of the claimed exons in that gene sequence and the identity and nucleotide numbering of the exons in which specific nucleotides are claimed at specific numbered positions and without knowing the relationship between the nucleotide positions claimed in SEQ ID NOS:2-4, 6, 8, 10 and 12 and the claimed BRCA2 sequence or the relationship of the amino acid positions claimed in SEQ ID NOS:5, 7, 9, 11 and 13 to the amino acid sequence "corresponding to" the claimed BRCA2 sequence. No positional relationship is provided in the disclosure for the exons 5, 15 and 16 or nucleotide positions recited in the claims because in the Sequence Listing each exon is a separate sequence with its own nucleotide numbering independent of the gene sequence nucleotide numbering and the exons presented in the figures have no nucleotide numbers. Applicant has indicated in the amendment filed September 18, 2000 that a corrected Sequence Listing paper copy and CRF "will follow". However, such Sequence Listing has not been received.

(b) Claim 62 is confusing due to the insertion of the extraneous word, "by", at line 2. It is suggested to delete the offending word.

#### Conclusion

6. No claim is allowed.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MEP. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action.

In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephanie Zitomer whose telephone number is (703) 308-3985. The examiner can normally be reached on Monday through Friday from 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152. The official fax phone number for this Group is (703) 308-4242. The unofficial fax number is (703) 308-8724.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

*S. Zitomer*  
Stephanie Zitomer, Ph.D.  
November 29, 2000

*Stephanie Zitomer*  
PRIMARY EXAMINER